## REMARKS

Claims 1 and 3-11 are now in this application, and are presented for the Examiner's consideration.

## Prior Art Rejections

Claims 1, 3, 5-8 and 11 were rejected under 35 U.S.C. \$102(b) as being anticipated by U.S. Patent No. 4,915,102 to Kwiatek et al.

Kwiatek et al was cited for disclosing, in Fig. 9, a single-use packaging for a liquid comprising a protective cover 4a/6a, breakable leak proof blister 17, pouch 15 affixed to the inside face of part 4a and applicator 23.

It is noted that there is a distinct difference between Kwiatek et al and the present invention with regard to structure of the capsule (blister or reservoir), as well as to use thereof.

In Kwiatek et al, the active agent carrier 15 including the reservoir 17 includes an active agent impermeable layer (19) on one side and an active <u>permeable</u> membrane (21, 23) on the other side. This is necessary in Kwiatek et al in order to deliver the contents of reservoir 17 to the skin of the person. If membranes 21, 23 were not permeable, Kwiatek et al would be inoperable for its intended purpose.

On the other hand, the blister of the present invention includes an impermeable film on <u>both</u> sides thereof. See page 4, lines 15-17 where it is stated that the blister of the present

invention is leaktight and only releases the material therein when broken. Since the blister is leaktight, the membranes thereof must be impermeable.

In Kwiatek et al, the reservoir 17 is not breakable. Both the membranes 21, 23 are permeable. However, since the carrier 15 including the reservoir 17 is housed between the two outer impermeable sheets 4a and 6a, it does not leak. It is only when sheets 4a and 6a are opened, and the carrier 15 including the reservoir 17 is adhered to the skin, does the liquid in reservoir 17 leak through membranes 21, 23 to the skin.

With the present invention, the blister (capsule) is breakable, whereupon the applicator is wetted with the substance once the blister has been broken. This operation is performed by applying pressure to the protective cover prior to opening it.

In this regard, claim 1 specifically recites a <u>breakable</u> <u>leakproof</u> blister containing one dose of said substance for application to skin of a person. As discussed above, carrier 15 including the reservoir 17 is not breakable, and clearly, it is not leakproof, since otherwise, it would be inoperable for its intended purpose.

In this regard, it is noted that claim 1 recites three distinct elements:

 a) a protective cover made of two separable parts of leakproof material,

- b) a breakable leakproof blister containing one dose of said substance for application to skin of a person, and
- c) a pouch comprising an applicator, and containing the blister therein, with the pouch fixed to an inside face of one of said two separable parts.

In Kwiatek et al, there is a protective cover made of leakproof material, namely, elements 4a, 6a.

Reservoir 17 was deemed to be the claimed blister. However, as discussed above, membranes 21, 23 are both permeable, and therefore, are not leakproof, as claimed. Further, reservoir 17 is not breakable to release the material therein, as claimed.

Carrier 15 was cited as the claimed pouch. However, carrier 15 only includes a pocket or recess (column 17, lines 46-47) partially surrounding the reservoir 17, but open at the lower end in Figs. 9-11.

In order to more clearly distinguish from Kwiatek et al, claim 1 has been amended to recite that the pouch completely surrounds the blister on all sides thereof. If the impermeable carrier 15 completely surrounded the blister on all sides, then Kwiatek et al would not be operable for its intended purpose.

In addition, claim 1 recites that the pouch includes an applicator. If element 15 is the claimed pouch, then it is open at its lower end and does not include an applicator. This is because the lower wall 21 is part of the reservoir, which was equated with the blister and not with the pouch.

Further, in Kwiatek et al, it is <u>essential</u> for the operation thereof, that the reservoir 17 and carrier 15 be released from the sheets 4a, 6a in order to be applied to the skin of the person, as shown in Fig. 11. With the present invention, on the other hand, the pouch containing the broken blister is <u>permanently</u> fixed <u>in operation</u> to the protective cover sheets. Of course, anything can be destroyed and taken apart, and for this reason, claim 1 recites the permanent fixation in operation, which is completely contrary to Kwiatek et al. In fact, if this limitation applies to Kwiatek et al, Kwiatek et al would be inoperable for its intended purpose.

Thus, claim 1 recites the following distinctions over Kwiatek et al:

- a) a breakable leakproof blister,
- b) a pouch comprising an applicator,
- c) the blister is housed in the pouch with the pouch completely surrounding the blister on all sides thereof,
- d) the pouch is <u>permanently</u> fixed <u>in operation</u> to an inside face of one of said two separable parts, and
- e) the applicator is impregnated with the substance when the blister is broken.

Claim 11 has been amended in the same manner as claim 1.

Accordingly, it is respectfully submitted that the rejection of claims 1, 3, 5-8 and 11 under 35 U.S.C. §102(b) has been overcome.

Claim 4 was rejected under 35 U.S.C. \$103(a) as being obvious from Kwiatek et al in view of U.S. Patent No. 4,762,124 to Kerch et al.

The remarks previously made above in regard to Kwiatek et al are incorporated herein by reference.

Kerch et al was merely cited for teaching the use of cotton wool 20 inside an applicator 10 with a permeable membrane 22. However, Kerch et al fails to cure any of the aforementioned deficiencies of Kwiatek et al.

It was stated that it would have been obvious to include cotton wool inside the pouch of Kwiatek et al. However, as discussed above, carrier 15 which was equated with the claimed pouch has a pocket or recess for holding reservoir 17, and is therefore open at the lower end in Figs. 9-11.

It is therefore submitted that there is nowhere to place the cotton wool in Kwiatek et al. If the cotton wool is placed in the pocket of carrier 15, it would have to be in surrounding relation to the sides and top of reservoir 17 to prevent the cotton wool from falling out of the open lower end. However, the sides and top of reservoir 17 are formed by impermeable wall 19, which would make the cotton wool ineffective. If the cotton wool is placed in reservoir 17, then, since reservoir 17 was equated with the claimed blister, it would be placed in the blister, and not in the pouch, as claimed.

Accordingly, it is respectfully submitted that the rejection of claim 4 under 35 U.S.C. \$103(a) has been overcome.

Claims 9 and 10 were rejected under 35 U.S.C. \$103(a) as being obvious from Kwiatek et al in view of PCT Patent Publication No. WO 02/02042 to Wendel et al, which corresponds to U.S. Patent No. 7,240,790.

The remarks previously made above in regard to Kwiatek et al are incorporated herein by reference.

Wendel et al discloses a single-use package equipped with two sheets impregnated with liquid and/or dressing. This package is used for application of pharmaceutical or cosmetic compositions to the skin. The package comprises a single piece of waterproof film, and thus, the package is sealed such that the film is folded.

Specifically, in Wendel et al, there is a protective cover including two separable leakproof pieces (1, 3 in Fig. 1; 12, 13 in Fig. 4 and 33, 34 in Fig. 5) that are fixed at their peripheries. This would correspond generally to protective cover (12) including two separable leakproof pieces (13, 14) of material of the present invention.

Wendel et al also provides for a material (2, 14, 32) that is impregnated with the product to be applied. The impregnated support is <u>fixed</u> to both strips (1, 3; 12, 13; and 33, 34). The

impregnated material (2, 14, 32) of Wendel et al would correspond to the cotton wool (32) of the present invention.

However, there is no disclosure or even a remote suggestion in Wendel et al of providing a breakable leakproof blister containing one dose of said substance for application to skin of a person, and a pouch comprising an applicator, wherein said blister is housed in said pouch with said pouch completely surrounding said blister on all sides thereof, said pouch is permanently fixed in operation to an inside face of one of said two separable parts, and said applicator is impregnated with said substance when said blister is broken.

Rather, the entire applicator of Wendel et al is comprised of a <u>single sheet</u> impregnated with a liquid composition. There is no disclosure or even a remote suggestion in Wendel et al of a pouch forming the applicator and which houses the blister, according to the present claimed invention.

Because of this construction of Wendel et al, the impregnating composition contained therein is restricted only to a liquid with a low viscosity. Moreover, the liquid within the sheet (2, 14, 32, 36) must be of a relatively small quantity.

As a result of the structure of the present claimed invention, the blister and pouch can hold <u>any type of</u> composition therein, including not only liquid, but also a greasy substance and even powder. This is because these substances are contained <u>inside the applicator</u> formed by the <u>additional piece</u> of flexible

and porous material fixed to said inside face of the leakproof sheet, with the material in which the substance is distributed being housed between said piece of flexible and porous material and the inside face of one leakproof sheet. This is very different from Wendel et al which merely impregnates a single sheet (impregnated support) 14 fixed to an inside face of one of the leakproof pieces of material 12, 13.

Furthermore, because of this structure, in addition to the different types of substances held therein, a large quantity of the substances can be retained therein. To increase the capacity, a bulky material such as cotton wool or the like can be contained between the protective cover and the piece of flexible and porous sheet.

Accordingly, it is respectfully submitted that the rejection of claims 9 and 10 under 35 U.S.C. §103(a) has been overcome.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee,

or any other fee required in connection with this Paper, to Account No. 07-1524.

The Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1524.

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1 and 3-11 are allowable, and early and favorable consideration thereof is solicited.

Respectfully submitted,

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